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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/729,028	12/04/00	YU S	6560

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EXAMINER	
USTRUP,C	

ART UNIT	PAPER NUMBER
1619	2

DATE MAILED: 09/13/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/729,028	YU ET AL.	
	Examiner	Art Unit	
	Clinton Ostrup	1619	

-- The MAILING DATE of this communication appears on the cover sheet with th correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claims 1-14 are pending in this application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and confusing because it describes a composition comprising an alcohol or mixture thereof. How can a composition contain a mixture of **an** alcohol? It is unclear if the "mixture thereof" is referring to a mixture of different alcohols or a mixture of the same alcohol at differing concentrations.

Claim 1 is further vague and indefinite because it describes a "sufficient quantity" to grow hair. The metes and bound of what constitutes a "sufficient quantity" are not clear in this claim.

Claims 2-3 and 6-7 are confusing because it is unclear what limitations are being added to the **composition**. It appears these claim

limitations should be directed to claims for methods of using the composition, not the composition itself.

Claim 4 is vague and indefinite because "primarily alcohol" is a relative term. The concentration range of ethanol is undeterminable from the description in claim 4.

Claim 5 is confusing because it is unclear what the volume percentages as claimed are based upon. Are they based on the volume of the total liquid composition?

Claim 6 is vague and confusing because it is unclear what constitutes "a portion of the stratum corneum." How much of the stratum corneum is removed? Further, is the portion of stratum corneum being removed from the skin wherein alopecia has occurred or somewhere else on the canine's body?

Claim 8 is vague and indefinite because the application of the composition of claim 1 could be anywhere on the canine or feline's skin. It does not require application of the composition of claim 1 to the area of skin where alopecia has occurred.

Further, the metes and bounds of Claim 8 are unclear because the terminology "quantities and frequency sufficient" to grow hair. The quantity

and frequency are not defined by the claim and since hair will grow on canines and felines without the application of the composition of claim 1, this claim reads on not applying the composition of claim 1 to the canine or feline at all.

Claim 11 is rejected for reasons analogous to claim 4.

Claim 12 is rejected for reasons analogous to claim 5.

Claim 13 is rejected for reasons analogous to claim 6.

Claims 2-14 are vague and confusing because they depend from claim 1 which is vague, confusing, and indefinite for the reasons stated above.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 6-11, and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Schwen et al 5,344,651.

Schwen et al teach methods of regulating hair growth by topical application of compositions comprising cyproterone acetate thioacetate (CATA). The reference describes how domestic animals such as cats and dogs suffer from hair loss and teaches methods for regulating hair loss by topical application of said compositions. The reference describes liquid formulations of the compositions as comprising a solution of a safe and effective amount of CATA and the balance being a mixture of water and/or a suitable organic solvent. Ethanol, isopropanol, or mixtures thereof are then described as organic materials useful as solvents or as part of a solvent system, therefore, Schwen et al meets the specific limitations of instant claims 1-4, and 6-9, 11, and 14. See: col. 1 lines 5-8; col. 2, lines 62-67; col.6, lines 3-13; and col. 11, lines 41-55.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-12 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gibson **4,871,839** and further in view of Schwen et al **5,344,651** as applied to claims 1-4, and 6-11, and 14 above.

Gibson teaches skin treatment compositions which are particularly suited to stimulate hair growth or regrowth. The primary reference discloses vehicles for topically administering formulations comprising minoxidil glucuoronide. The vehicles are described as water and/or at least one cosmetically acceptable vehicle which can comprise from 10 to 99.999% by weight of the composition. The primary reference teaches ethyl alcohol (ethanol) and isopropanol as solvents, which can be used as cosmetically acceptable vehicles. See: col. 6, line 30 – col. 7, line 40.

Although Gibson describes using ethanol and isopropanol containing compounds in concentrations, which overlap those of instant claims 5 and 12 to grow hair, Gibson does not specifically teach using these compounds to grow hair on canines and felines.

Schwen et al teach methods of hair growth comprising application of cyproterone acetate thioacetate (CATA) and compositions comprising CATA. The reference describes how domestic animals such as cats and dogs suffer from hair loss and describes methods for regulating hair loss by topical application of compositions containing alcohol. The secondary reference teaches ethanol, isopropanol, or mixtures thereof as the solvents or as part of a solvent system. See: col. 1 lines 5-8; col. 2, lines 62-67; col.6, lines 3-13; and col. 11, lines 41-55.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the method of using the hair growth compositions of Gibson by topically applying the hair growth compositions to canines and felines as taught by Schwen et al, because of the expectation of obtaining a method of regulating hair growth in domestic animals such as cats and dogs.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schwen et al as applied to claim 1-12 and 14 above, and further in view of Jacques et al **4,775,361**.

Schwen et al teach the topical application of compositions comprising ethanol and isopropanol and the use of said compositions as regulating hair growth in domestic animals including cats and dogs, however, Schwen et al do not specifically teach the removal of a portion of the stratum corneum prior to the application of alcohol as in claim 13.

Jacques et al disclose a method of administering a polar therapeutic substance by first removing the stratum corneum to enhance percutaneous transport and then applying the polar therapeutic substance. The secondary reference specifically discloses tape stripping as a method of removing the stratum corneum and applying the therapeutic substance after the stratum corneum has been removed. See: col. 1, lines 5-32.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the methods of using a the topical hair growth composition of Schwen et al. by removing the stratum coneum by tape stripping as taught by Jacques et al because of the expectation of obtaining a method of applying a topical hair growth

composition for percutaneous transport which does not have to overcome the skin barrier function of the stratum corneum.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Clinton Ostrup whose telephone number is (703) 308-3627. The examiner can normally be reached on M-F (8:30am-5:00pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Diana Dudash can be reached on (703) 308-2328. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Clinton Ostrup
Examiner
Art Unit 1619

September 9, 2001

DIANA DUDASH
SUPERVISORY PATENT EXAMINER
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